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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,256	02/13/2002	Barry N. Kreiswirth	19124.0012	7913
23517	7590	10/15/2003	[REDACTED]	[REDACTED] EXAMINER LY, CHEYNE D
SWIDLER BERLIN SHEREFF FRIEDMAN, LLP				
3000 K STREET, NW				
BOX IP			[REDACTED]	[REDACTED] ART UNIT 1631
WASHINGTON, DC 20007				

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/073,256	KREISWIRTH ET AL.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 22 August 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) 1-37 and 39-49 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 38 and 50 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-50 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 07/03.      6) Other: *Search Result 3*.

### **DETAILED ACTION**

1. Applicant's election with traversal of Group I, claims 13, 25, 38, and 50, SEQ ID 54 and *Staphylococcus aureus*, filed August 22, 2003 is acknowledged.
2. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. The requirement is still deemed proper and is therefore made FINAL.
4. Claims 1-37 and 39-49 have been withdrawn due to the claimed subject matter not being directed to the elected subject matter.
5. Claims 38 and 50, SEQ ID 54 and *Staphylococcus aureus*, are examined on the merits.

### **OBJECTIONS**

6. The title of the invention is not descriptive because the claimed invention is directed to a method while the instant is directed to a system and method. A new title is required that is clearly indicative of the invention to which the claims are directed.

### **NEW CLAIM REJECTIONS - 35 USC § 102**

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 38 and 50 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hoe et al. (April 1999).

9. The method of Hoe et al. for identifying and tracking an outbreak of an infection wherein said method comprises comparing sequences to a database (GenBank database, Figure 1) having the sequence of a staphylococcus aureus strain (GenBank Acc. No. AJ224764). The samples gathered by the Texas Department of Health and analyzed at Baylor College of Medicine (remote facility) (page 255, Brief Overview of the GAS Epidemiology) sequencing the sic gene wherein a region contains repeat sequences to unambiguously differentiate 30 M1 isolates recovered from 28 patients in Texas (Abstract etc.). The sequenced nucleic acid molecules are used to search an emm database maintained in the laboratory (page 255, column 2, Sequence Analysis of emm §, lines 3-10 and Figure 4), as in instant claims 28-30. M1 isolates cultured from patients share a common ancestor and lack readily detectable chromosomal variation (phylogenetic relatedness)(page 254, column 2, lines 2-13 and Figure 1). The database contains sequences from global sources (page 255, lines 28-30) and GenBank, Bethesda, MD, (Figure 1) (database of historical sample containing the sequence of SEQ ID NO. 54).

10. The GenBank document comprising the sequence of AJ224764 of a staphylococcus aureus strain which is identical to SEQ ID NO 54 (Search Result 3) of this instant application is provided to disclose that the GenBank database at the time of the inventing comprises at least the sequence of SEQ ID NO. 54. Therefore, the limitations, method steps and staphylococcus aureus microorganism, of the instant application are clearly anticipated by the disclosure of Hoe et al.

## **CONCLUSION**

11. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the

Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

14. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
10/9/03

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER